REMARKS

Claims 1-49 were presented.

Claims 6-10, 23-26, 31-35, and 46-49 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Office Action asserts that the specification lacks a disclosure of how to detect whether a patient is a neonate.

Claims 1-5 and 27-30 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,759,157 to Harada et al. (hereinafter "Harada").

Claims 11-13 and 36-38 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of U.S. Patent No. 6,405,076 to Taylor et al. (hereinafter "Taylor").

Claims 14-17, 21-22, 39, 40, and 44-45 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Taylor, and further in view of U.S. Patent No. 4,870,973 to Ueno (hereinafter "Ueno").

Claims 18-20 and 41-43 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Taylor and Ueno, and further in view of U.S. Patent No. 4,592,365 to Georgi (hereinafter "Georgi").

Independent claims 1 and 27 have been respectively amended to recite in relevant part:

"a first analysis module, said first analysis module configured to analyze said signal during an inflation of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated to extract from said signal said blood pressure of said vertebrate;"

and

"analyzing said signal during an inflation of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated to extract from said signal said blood pressure of said vertebrate."

Support for the amendments is found throughout the Specification as filed, and at least at paragraph [00044] as originally filed, which recites in relevant part:

> ... The fast cycle comprises inflating the cuff 102 and sensing pressure/volume signals with sensor 106. The sensor electronic module 108 comprises a control module configured to receive as input at least a portion of the signal from the sensor 106, and to generate as output a control signal having a selected one of a plurality of values responsive to said input. As indicated by box 206, a determination is made as regards the extent of motion (or other artifacts) distinct from the expected signal indicative of a blood pressure measurement. A motion detection module configured to receive as input at least a portion of the signal from the sensor performs the determination. Depending at least in part on the magnitude of the control signal, the blood pressure signal is deemed to be suitable for analysis or unsuitable. The signals so sensed are analyzed using a first analysis module. As indicated by box 207, the analyzed information is evaluated to determine of the answer appears to be correct. If the answer appears to be correct, and the blood pressure measurement so arrive at is deemed appropriate, an "answer" or result is obtained, and in some embodiments is enunciated at box 210. ...

Examiner Nasser is thanked for a telephonic interview that took place on March 14, 2007, in which the undersigned participated. The interview discussion covered the rejection of the claims under 35 U.S.C. §102(b), the cited art, and the claims. The Applicant proposed claim language to distinguish the invention over the cited art. There was agreement that the proposed claim language, presented herein as amendments, would distinguish the invention over the cited art. The Examiner requested evidence that the claimed invention operates at a speed of inflation faster than the conventional or accepted speed at which measurements of blood pressure are performed heretofore (e.g., that the conventional or accepted speed at which blood pressure measurements are made is 2 to 3 mmHg per second). The Examiner indicated that a further search would be required, which search might disclose further material art.

Applicants submit herewith a Declaration under 37 C.F.R. §1.132 that demonstrates that the conventional or accepted speed at which blood pressure measurements are made heretofore is 2 to 3 mmHg per second.

Response to Rejection of Claims 6-10, 23-26, 31-35, and 46-49 under 35 U.S.C. §112, 1st paragraph

Claims 6-10, 23-26, 31-35, and 46-49 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Office Action asserts that the specification lacks a disclosure of how to detect whether a patient is a neonate.

Applicants respectfully submit that the Specification as filed contains the following statement at paragraph [00043] of the originally filed application (paragraph [0038] in the application as published as US 2005/0033188 A1):

> The process starts at box 202, labeled "Start," that will be understood to represent all of the steps of initiating operation of the microprocessor-based blood pressure measurement apparatus, including all necessary initial internal testing and diagnostic routines to assure proper operation of the apparatus, as well as operator entry of information needed to identify the subject vertebrate and the circumstances of the measurement. As described hereinbefore, the operator can enter information using any or all of a keyboard, a button, a mouse (in conjunction with a Graphical User Interface (GUI), a menu system, or the like), and/or audible entry of information with a microphone. As required, initialization information can also be downloaded from a database. In order to commence a measurement of the blood pressure of a vertebrate, the operator places the necessary inflatable chamber or cuff on the appropriate location of he vertebrate to be tested, such as an arm of a human being, and confirms that all of the necessary portions of the apparatus are properly made ready. The operator then issues a command to initiate the measurement, such as pressing a button. In one embodiment, at box 204, the apparatus performs an analysis of the signals that it detects to determine whether the subject vertebrate is a neonate. Alternatively, the operator can issue a command indicating that the subject is or is not a neonate.

Applicants clearly described one alternative, namely that an operator informs the apparatus that the subject is a neonate. Applicants also described that information can be downloaded from a database. The Specification include the following statement: An example of a neonate vertebrate is a human having an age of 28 days or less since birth. If the database includes such normal information as a date of birth, and the apparatus uses such conventional information as the current date and time in reporting test results, it would be a straightforward

matter for the apparatus to determine whether a particular subject was younger or older than 28 days. This is a second way in which the apparatus can determine if the subject is a neonate. A third way that an apparatus can determine if a subject is a neonate involves well-known technology, namely identifying a size of a blood pressure cuff used to measure the blood pressure of the subject. U.S. Patent No. 5,022,403, issued on June 11, 1991 to LaViola and assigned to CAS Medical Systems, Inc., describes an apparatus for measuring blood pressure that distinguishes between an adult blood pressure cuff and a pediatric blood pressure cuff. The Abstract teaches:

> ... For example, the device can employ an adult cuff, or a pediatric cuff. To accomodate the different cuff sizes, the device has more than one bleed orifice with which it controls the deflation steps. The onboard computer is programmed to use a selected one of the bleed orifices in the first bleed step and to use the time duration of the first bleed step to determine what size cuff is being used. Once the cuff size is determined, the proper bleed orifice designed for the determined cuff size is made operative, and the testing continues. ...

Applicants have also found, using the web archives available through www.archive.org, that the web site of CAS Medical Systems, Inc. (www.casmed.com) as early as April 14, 2000 included neonatal products, including a neonate blood pressure cuff referred to as a Pedisphyg Blood Pressure Cuff. The web page states: "sizes available to fit any infant." Copies of the relevant pages are appended hereto for the convenience of the Examiner.

Applicants respectfully submit that they have explicitly explained at least one way, and possibly two ways, that the apparatus can determine if a subject is a neonate, and that additionally, such a determination is well-known in the patent literature, for example by determining whether a blood pressure cuff of a size suitable for a neonate is being used. Applicants further make note of MPEP 2164.01, which states in relevant part: "A patent need not teach, and preferably omits, what is well known in the art."

Response to Rejection of Claims 1-5 and 27-30 under 35 U.S.C. §102(b)

Claims 1-5 and 27-30 stand rejected under 35 U.S.C. §102(b) as being anticipated by Harada. Presently amended independent claims 1 and 27 are the only independent claims pending in the application.

As is explained in U.S. Patent No. 4,860,759, the entire disclosure of which was incorporated by reference into the present application, a common rate of deflation of a blood pressure cuff during a measurement is 3 millimeters of mercury (3 mm of Hg) per second. Conventionally, if blood pressure is being measured during an increase of pressure in the cuff, the same 3 mm of Hg per second rate of change is used. By comparison, in the present invention, in which "fast" inflation and deflation rates are used, the fast rate is at least 5 mm of Hg per second, and can be 10 mm of Hg per second.

Harada teaches a method of measuring blood pressure. Harada teaches that the blood pressure measurements are performed during either a slow inflation period and a slow deflation period of the blood pressure cuff (see Fig. 4 of Harada; see steps SA3 and SA10 of Figs. 3 and 6 of Harada). Harada teaches at column 5, lines 43-48, that

> At Step SA3, the pressure regulating valve 14 is switched to a slow-inflation position in which the pressure regulating valve 14 permits the pressurized air to be supplied to the cuff 10 at a rate suitable for blood pressure measurements, for example, 2 to 3 mmHg/sec, as shown at point t_2 in FIG. 4

Harada teaches at column 6, lines 24-29, that

> At Step SA10, the pressure regulating valve 14 is switched to a slow-deflation position in which the cuff pressure P_c is slowly decreased at a rate suitable for blood pressure measurements, for example, 2 to 3 mmHg/sec, as indicated at broken line in FIG. 4.

Applicants respectfully submit that Harada does not teach or suggest "a first analysis module, said first analysis module configured to analyze said signal during an inflation of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is

fully inflated to extract from said signal said blood pressure of said vertebrate;" or the corresponding analysis step.

Because Harada fails to teach or suggest either a first analysis module, said first analysis module configured to analyze said signal during an inflation of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated to extract from said signal said blood pressure of said vertebrate or the corresponding analysis step, Harada fails to anticipate independent claims 1 and 27 as presently amended. Applicants respectfully submit that independent claims 1 and 27 are patentable over Harada. Applicants further submit that claims 2-26 which depend from independent claim 1, and claims 28-49 which depend from independent claim 27 are patentable as depending from allowable base claims.

Response to Rejection of Claims 11-13 and 36-38 under 35 U.S.C. §103(a)

Claims 11-13 and 36-38 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Taylor.

Taylor teaches methods of filtering blood pressure measurement signals to remove artifacts.

At column 5, lines 1-12, Taylor teaches:

> Also as is known to those skilled in the art, apparatus 10 is usable to measure a subject's blood pressure and heart rate during a suitable measurement cycle. For practicing the present invention, the usual NIBP-cycle may be used as a measurement cycle in the practice of the present invention. Such cycle includes monitoring and processing pressure-signal information from cuff 16 for a defined range of pulsatile information, i.e. from a supra-systolic pressure (cuff inflated) to below diastolic pressure (cuff deflated preferably gradually). Gradual cuff deflation is preferred because it optimizes patient comfort and promotes accuracy of data measurement because, in stepwise cuff deflation, data occuring during step deflation can be lost.

At column 5, lines 61-67, Taylor teaches:

> As used herein, filtering of data means to take an input signal carrying data, and perform preselected mathematical operations on that data to produce filtered data. The specific type of filtering presently contemplated by the invention involves removing noise (also referred to as artifact) from the data. The filtering of the PRESSURE/ECG data can be done using any suitable filter.

At column 8, lines 36 to 42, Taylor teaches that

> Signal noise is estimated by comparing the real-time incoming signal with the composite signal averaged pulse. When noise is low the bleed rate can be set to the highest rate. With increasing noise, a slower bleed rate and a lower corner frequency filter is used. In extremely severe noise, the cuff pressure is held constant and signal ignored for up to ten seconds.

Taylor does not teach or suggest making a "a first analysis module, said first analysis module configured to analyze said signal during an inflation of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated to extract from said signal said blood pressure of said vertebrate;" or the corresponding analysis step.

Because Taylor fails to teach or suggest either a first analysis module, said first analysis module configured to analyze said signal during an inflation of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated to extract from said signal said blood pressure of said vertebrate or the corresponding analysis step, the combination of Taylor with Harada (assuming *arguendo* that such combination is shown to be motivated) fails to anticipate independent claims 1 and 27 as presently amended. Applicants reserve the right to argue that no motivation has been shown to combine Taylor with Harada. Applicants respectfully submit that independent claims 1 and 27 are patentable over the combination of Taylor with Harada. Applicants further submit that claims 11-13 which depend from independent claim 1, and claims 36-38 which depend from independent claim 27 are patentable as depending from allowable base claims.

In addition Applicants note for the record that the Examiner has a burden of demonstrating that there exists a motivation, suggestion, or teaching to combine the teachings of

two or more patents, which motivation, suggestion, or teaching must be found independent from the teachings of the application being examined. See *In re Werner Kotzab*, 217 F.3d 1365 (CAFC, 2000).

The CAFC stated in *Kotzab* at pages 1369-70 (citations omitted):

> Most if not all inventions arise from a combination of old elements. Thus, every element of a claimed invention may often be found in the prior art. However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference.
>
> The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved. In addition, the teaching, motivation or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references. The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art. Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. Broad conclusory statements standing alone are not "evidence."

Response to Rejection of Claims 14-17, 21-22, 39, 40, and 44-45 under 35 U.S.C. §103(a)

Claims 14-17, 21-22, 39, 40, and 44-45 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Taylor, and further in view of Ueno.

Ueno teaches systems and methods of detecting artifacts in blood pressure measurements made with a meter. However, Ueno fails to teach or suggest a first analysis module, said first analysis module configured to analyze said signal during an inflation of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated to extract from said signal said blood pressure of said vertebrate or the corresponding analysis step.

Accordingly, combining Ueno with Taylor and Harada (assuming *arguendo* that such combination is shown to be motivated) fails to anticipate independent claims 1 and 27 as presently amended. Applicants reserve the right to argue that no motivation has been shown to combine Ueno with Taylor and with Harada. Applicants respectfully submit that independent claims 1 and 27 are patentable over the combination of Ueno, Taylor and Harada. Applicants further submit that claims 14-17, and 21-22 which depend from independent claim 1, and claims 39, 40, and 44-45 which depend from independent claim 27 are patentable as depending from allowable base claims.

Response to Rejection of Claims 18-20 and 41-43 under 35 U.S.C. §103(a)

Claims 18-20 and 41-43 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Harada in view of Taylor and Ueno, and further in view of Georgi.

Georgi teaches systems and methods of making blood pressure measurements made with an electronic meter. However, Georgi only teaches or suggests making the measurement during the deflation portion of an inflation-deflation cycle. Georgi teaches at column 23, lines 25 to 31 that:

> The measuring of blood pressure, in accordance with the present invention, is accomplished during a measurement cycle which consists of three basic segments:
>
> (1) The pump-up phase,
>
> (2) The deflation and data collection phase, and
>
> (3) The data analysis and computation of blood pressure and pulse rate phase.

Therefore, Georgi fails to teach or suggest a first analysis module, said first analysis module configured to analyze said signal during an inflation of said inflatable chamber at a rate greater than 3 mmHg per second before said inflatable chamber is fully inflated to extract from said signal said blood pressure of said vertebrate or the corresponding analysis step.

Accordingly, combining Georgi with Ueno, with Taylor, and with Harada (assuming *arguendo* that such combination is shown to be motivated) fails to anticipate independent claims 1 and 27 as presently amended. Applicants reserve the right to argue that no motivation has been shown to combine Georgi withUeno, with Taylor, and with Harada. Applicants respectfully submit that independent claims 1 and 27 are patentable over the combination of Georgi, Ueno, Taylor and Harada. Applicants further submit that claims 18-20 which depend from independent claim 1, and claims 41-43 which depend from independent claim 27 are patentable as depending from allowable base claims.

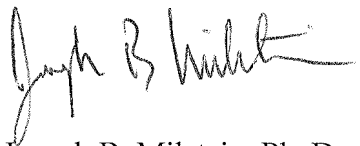
CONCLUSION

Claims 1-49 are pending in the application.

For the reasons given above, Applicants respectfully request that the application be reconsidered and that the rejections of Claims 1-49 be withdrawn. Applicants submit that Claims 1-49 are now in proper condition for allowance, and requests the issuance of a Notice of Allowance at the Examiner's earliest convenience.

If the Examiner believes that contact with Applicants' attorney would be advantageous toward the disposition of this case, the Examiner is requested to call Applicants' attorney at the phone number noted below.

Respectfully submitted,
HISCOCK & BARCLAY, LLP

By: 

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